

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

The effects of routine treatment and manual therapy on pain, and range of motion in patients with temporomandibular disorders

Protocol summary

Study aim

The effects of routine treatment and manual therapy in patients with temporomandibular disorders

Design

This study included two groups: control group and intervention group. study design: randomized control trial with control group, parallel group. The patients and outcome assessor will be blind

Settings and conduct

Place of study: Iran University of Medical Sciences, School of rehabilitation, Ultrasonography laboratory
Method: This study included two groups: control group and intervention group. Control group: The control group will receive the routine physiotherapy including gentle massage over the masseter muscle, ultrasound 1 MHz and TENS. The intervention group will receive the routine physiotherapy AND manual therapy of temporomandibular joint and upper cervical .

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-unilateral or bilateral TMD according to the DC/TMD 2-pain more than 3 based on visual analog scale Exclusion criteria: 1-a traumatic injury that caused the symptoms in the temporomandibular joint and the orofacial region during the last three months 2-history of the orofacial surgery during the last 6 months 3-neurological and systemic diseases such as rheumatoid arthritis; Parkinson; multiple sclerosis, positional vertigo, pregnancy, and severe deformity in the jaw or face region

Intervention groups

Control group: The control group will receive the routine physiotherapy such as massage, therapeutic ultrasound 1MHZ and TENS for eight weeks. Intervention group: The intervention group will receive the routine physiotherapy and manual therapy of TMJ and cervical spine. The patients in both groups will receive routine physiotherapy 10 sessions during eight weeks.

Main outcome variables

pain; maximum mouth opening, cervical flexion and

extension range of motions,

General information

Reason for update

Lack of time in coronary conditions

Acronym

IRCT registration information

IRCT registration number: **IRCT20190621043964N1**

Registration date: **2019-06-29, 1398/04/08**

Registration timing: **prospective**

Last update: **2021-07-19, 1400/04/28**

Update count: **1**

Registration date

2019-06-29, 1398/04/08

Registrant information

Name

Khaled Rezaie

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-01, 1398/08/10

Expected recruitment end date

2021-02-01, 1399/11/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of routine treatment and manual therapy on pain, and range of motion in patients with temporomandibular disorders

Public title

The effects of routine treatment and manual therapy in people with temporomandibular disorder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Individuals with unilateral or bilateral TMD according to the DC/TMD pain more than 3 based on visual analog scale

Exclusion criteria:

traumatic injury that caused the symptoms in the temporomandibular joint and the orofacial region during the last three months history of the orofacial surgery during the last 6 months neurological and systemic diseases such as rheumatoid arthritis; Parkinson; multiple sclerosis, positional vertigo, pregnancy, and severe deformity in the jaw or face region

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **30****Randomization (investigator's opinion)**

Randomized

Randomization description

Randomization method: Block balanced randomization design, block size:4, ratio 1:1 Randomization tool: Random allocation will be performed using the website of www.randomization.com.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

City

Tehran

Province

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Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2018-10-28, 1397/08/06

Ethics committee reference number

Ir.lums.Rec.1397.1054

Health conditions studied**1****Description of health condition studied**

Temporomandibular dysfunction

ICD-10 code

M26.6

ICD-10 code description

Temporomandibular joint disorders

Primary outcomes**1****Description**

pain

Timepoint

At the baseline, after the end of the treatment, and after a one-month follow-up period

Method of measurement

Visual analog scale

Secondary outcomes**1****Description**

Maximum mouth opening

Timepoint

At the baseline, after the end of the treatment, and after a one-month follow-up period

Method of measurement

caliper

2**Description**

Cervical flexion and extension ROM

Timepoint

At the baseline, after the end of the treatment, and after a one-month follow-up period

Method of measurement

Goniometer

Intervention groups

1

Description

Control group: The control group will receive the routine physiotherapy such as gentle massage over the masseter muscles , therapeutic ultrasound 1MHZ and TENS for ten sessions during 8 weeks.

Category

Rehabilitation

2

Description

Intervention group: The intervention group will receive the routine physiotherapy such as gentle massage over the masseter muscles , therapeutic ultrasound 1MHZ and TENS and manual therapy of the TMJ and upper cervical spine. This group will receive the interventions for ten sessions during 8 weeks.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Khaled Rezaie

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Rezaie Khaled

Position

Phd student of Physiotherapy, Iran University of
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Latest degree

Master

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The original data is shared in thesis format

When the data will become available and for how long

After defense of thesis, the original data is shared in
thesis format.

To whom data/document is available

Academic researchers, physiotherapists

Under which criteria data/document could be used

In order to use clinical results, the original data is shared
in thesis format.

From where data/document is obtainable

Library of the faculty of rehabilitation rehabilitation
Sciences of Iran University of Medical Sciences

What processes are involved for a request to access data/document

Referral to library of the faculty of rehabilitation Sciences
of Iran University of Medical Sciences

Comments